Exhibit 17

2016 WL 1222229
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United States District Court, D. Minnesota.

Lamar HODGES, Jr., Plaintiff,
v.
PFIZER, INC., Wyeth, LLC, and Wyeth Consumer Healthcare, Inc., Defendants.

Civil No. 14-4855 ADM/TNL
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Signed March 28, 2016

Attorneys and Law Firms

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MEMORANDUM OPINION AND ORDER

ANN D. MONTGOMERY, U.S. DISTRICT JUDGE

I. INTRODUCTION

***1** This matter is before the undersigned United States District Judge on Defendants Pfizer, Inc., Wyeth, LLC, and Wyeth Consumer Healthcare, Inc.'s (collectively, "Defendants ") Objections [Docket No. 173] to Magistrate Judge Tony N. Leung's December 17, 2015 Order [Docket No. 147] ("Discovery Order") granting in part and denying in part Plaintiff Lamar Hodges, Jr.'s ("Hodges") Motion to Compel Discovery [Docket No. 72]. For the reasons set forth below, Defendants' Objections are overruled.

II. BACKGROUND

Hodges ingested Advil when he was 16 years old and suffered a severe adverse drug reaction known as Stevens-Johnson Syndrome ("SJS ") / Toxic Epidermal Necrolysis ("TEN "). Am. Compl. [Docket No. 51] ¶ 8. A significant portion of his skin blistered and eventually sloughed off, requiring Hodges to be treated for a month at Regions Hospital Burn Center. Id. ¶¶ 19–20. The SJS / TEN reaction and the multiple operations left essentially no intact skin on his face, neck, scalp, trunk, back, buttocks, arms, and legs. Id. ¶ 22. As a result, Hodges is permanently disfigured, blind in one eye, and will likely lose all sight in the future. Id. ¶¶ 22–24.

Hodges commenced this action in November 2014 against the Defendants who manufacture and market Advil. Defendants responded by bringing a partial motion to dismiss, which the Court granted in part and denied in part. See Mem. Op. Order [Docket No. 36]. Hodges thereafter filed the Amended Complaint, asserting claims for failure to warn, defective design, fraud and fraudulent inducement, breach of express warranty, negligence, unjust enrichment, and violations of Minn. Stat. §§ 325D.13, 325F.67, and 325F.69. Am. Compl. ¶¶ 98–176.

After reaching an impasse regarding the proper scope of discovery, Hodges and Defendants each brought a motion to compel. Hodges' motion sought discovery of an array of information related to Advil, SJS / TEN, or Defendants, including: safety and testing data; communications with the FDA and foreign regulatory agencies; historical labeling changes; marketing materials; and financial information. See generally Pl.'s Mem. Supp. Mot. Compel [Docket No. 74]. Defendants' motion sought detailed information regarding Hodges' use of and adverse reaction to Advil, as well as production of documents underlying the allegations in the Amended Complaint. See generally Defs.' Mem. Supp. Mot. Compel [Docket No. 91]. Judge Leung, after a review of the dozens of discovery requests, partially granted each motion. See Discovery Order at 38.

On February 5, 2016, Defendants filed these Objections, arguing that Judge Leung erred in ordering Defendants to produce certain regulatory, financial, and sales and marketing documents.

III. DISCUSSION

A. Standard of Review

The standard of review applicable to an appeal of a magistrate judge's order on a nondispositive issue is extremely deferential. Reko v. Creative Promotions, Inc., 70 F. Supp. 2d 1005, 1007 (D. Minn. 1999). The district court must affirm an

order by a magistrate judge unless it is "clearly erroneous or contrary to law." Fed. R. Civ. P. 72(a). "A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." Chakales v. Comm'r of Internal Revenue, 79 F.3d 726, 728 (8th Cir. 1996). "A decision is 'contrary to the law' when it 'fails to apply or misapplies relevant statutes, case law or rules of procedure.' " Knutson v. Blue Cross & Blue Shield of Minn., 254 F.R.D. 553, 556 (D. Minn. 2008) (quoting Transamerica Life Ins. Co. v. Lincoln Nat'l Life Ins. Co., 592 F. Supp. 2d 1087, 1093 (N.D. Iowa 2008)).

B. Defendants' Objections

***2** Defendants object to the ordered production of three categories of documents: foreign regulatory documents, financial documents, and sales and marketing documents. Defendants argue that the Discovery Order is contrary to law with respect to these categories of documents because of their "limited, if any, relevance " to this dispute and Judge Leung's "failure to weigh the burdens and to analyze proportionality." Objs. at 2.

As of December 1, 2015, Rule 26 of the Federal Rules of Civil Procedure provides in pertinent part:

> **(b) Discovery Scope and Limits.**
>
> **(1)** ***Scope in General.*** Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Fed. R. Civ. P. Rule 26(b)(1). Federal Rule of Civil Procedure 26 is to be construed broadly and encompasses "any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case." In re Milk Prod. Antitrust Litig., 84 F. Supp. 2d 1016, 1027 (D. Minn. 1997) (quoting Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351 (1978)); Hofer v. Mack Trucks, Inc., 981 F.2d 377, 380 (8th Cir. 1992) ("Rule 26(b) ... is liberal in scope and interpretation"). To ensure Rule 26(b) is not "misapplied so as to allow fishing expeditions in discovery," a party must make a "threshold showing of relevance ... before parties are required to open wide the doors of discovery and to produce a variety of information which does not reasonably bear upon the issues in the case." Hofer, 981 F.2d at 380. The threshold requirement of discoverability is met if the information sought is "relevant to the subject matter involved in the pending action." Archer Daniels Midland Co. v. Aon Risk Serv., Inc. of Minn., 187 F.R.D. 578, 589 (D. Minn. 1999) (quoting Shelton v. Am. Motors, 805 F.2d 1323, 1326 (8th Cir. 1986)). "[T]he standard of relevance in the context of discovery is broader than in the context of admissibility." Hofer, 981 F.2d at 380.

The 2015 Amendment to Rule 26(b)(1) relocated and slightly revised the proportionality language formerly located in subdivision (b)(2)(C)(iii). Fed. R. Civ. P. 26 at advisory committee's note to 2015 amendment. In doing so, the amendment "restores the proportionality factors to their original place in defining the scope of discovery " but "does not change the existing responsibilities of the court and the parties to consider proportionality." Id.

1. Foreign Regulatory Documents

Judge Leung ordered Defendants to produce "foreign documents concerning single-ingredient, adult ibuprofen products between 2001 and 2010 (a) from France, the United Kingdom, the Netherlands, Germany, Japan, Australia, or Taiwan (b) pertaining to (i) labeling and package inserts, (ii) adverse events and pharmacovigilance, (iii) regulatory actions and correspondence with regulatory authorities, or (iv) restrictions or withdrawals from the market." [1] Discovery Order at 13.

***3** Defendants argue that such documents have no more than *de minimis* relevance to this dispute. However, as Judge Leung noted, such documents are relevant to Defendants' knowledge of the risks of SJS / TEN, which in turn is relevant to Hodges' claims. See, e.g., In re Levaquin Prods. Liab. Litig., 700 F.3d 1161, 1166 (8th Cir. 2012) ("A plaintiff asserting a negligent failure-to-warn claim under Minnesota law must show: (1) the defendant had reason to know of the dangers of using the product ....") (quotation omitted). The cases Defendants cite on this point are inapposite because they are directed to the admissibility of foreign regulatory documents at trial, and evidence need not be admissible to be

discoverable. Fed. R. Civ. P. 26(b)(1). Significantly, in at least one of the cases cited by Defendants, the court previously ordered production of foreign regulatory documents. In re Seroquel Prods. Liab. Litig., No. 6–1769, 2008 WL 508391, at *2–3 (M.D. Fla. Feb. 21, 2008).

Next, Defendants argue that production of foreign regulatory documents would duplicate information already reflected in a global pharmacovigilance and adverse event database. But that database has, on its face, a more limited scope than the set of foreign documents ordered to be produced, of which "adverse events and pharamacovigilance" is only a subset. Discovery of these documents, therefore, will not be "unreasonably cumulative or duplicative" of the information available in the database. Fed. R. Civ. P. 26(b)(2)(C)(i); see Progressive Cas. Ins. Co. v. F.D.I.C., 49 F. Supp. 3d 545, 563–64 (N.D. Iowa 2014) (overruling objection to discovery order requiring a non-party to produce documents that may overlap documents already produced in the case).

Finally, Defendants argue that Judge Leung failed to consider the burdens and proportionality of requiring Defendants to produce foreign regulatory documents. Judge Leung discussed the 2015 amendment to Rule 26 at the beginning of the Discovery Order and explicitly relied on the burden and proportionality factors to deny a different part of Hodges' motion to compel. Discovery Order at 4–6, 17. Although Judge Leung did not discuss burden or proportionality in the subsection of the Discovery Order addressing foreign documents, he did narrow the extent of required production to seven countries and three subject areas. Because there is no relevance-based reason to so limit discovery—notice of the risks of SJS / TEN could conceivably originate from any country—the Court is not left with the "definite and firm conviction" that Judge Leung failed to consider the burden and proportionality factors with respect to these documents. Chakales, 79 F.3d at 728.

Because the foreign regulatory documents at issue meet the threshold relevance requirement and their production would not be overly burdensome or disproportionate to the needs of the case, Judge Leung's Discovery Order compelling production of the same is neither erroneous nor contrary to law.

2. Financial Documents

Judge Leung ordered Defendants to produce: financial documents regarding the sums Defendants spent on Advil and serious skin reactions between 2001 and 2010; profits (gross and net) for sales of Advil in the United States between 2001 and 2010; and sales forecasts, advertising budgets, business plans, marketing plans, and financial plans for Advil in the United States between 2001 and 2010. Discovery Order at 24.

Defendants argue that Judge Leung erred by noting the relevance of financial information to a punitive damages assessment even though Hodges has not made the prima facie showing required to seek punitive damages. This argument is not well-taken, particularly since it was Defendants who raised the topic of punitive damages. See Defs.' Mem. Opp. Pl.'s Mot. Compel [Docket 98] at 38–39. Judge Leung's statement was an acknowledgment that a punitive damages assessment is one, but not the only, potentially relevant use of the financial documents. He further explained how the documents could be relevant to the merits of Hodges' claims: "information about sales goals, projections, and trends 'is certainly relevant particularly when it may impact decision making regarding labeling. There is an inherent tension between the desire for profit and scientific decisions that suggest warnings that may well shrink the customer base because of cautionary tone struck by the warnings.' " Discovery Order at 23 (quoting In re Yasmin and YAZ (Drospirenone) Mktg., Sales Practices & PMF Prods. Liab. Litig., No. 9-2100, 2011 WL 6740391, at *10 (S.D. Ill. Dec. 22, 2011)). Furthermore, "excessive concern with the image and marketing of those drugs at the expense of making efforts towards determining whether they were safe could be probative as to whether the manufacturer breached a duty of care towards the plaintiffs." Id. at 23-24 (quoting In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 369 F.3d 293, 314 (3d Cir. 2004)). Defendants' Objections ignore these other potentially relevant uses of the financial documents.

***4** Because the financial documents are relevant to the issues in this dispute whether or not there is a viable claim for punitive damages, Judge Leung's Discovery Order compelling production of the same is neither erroneous nor contrary to law.

3. Sales and Marketing Documents

Lastly, Defendants object to the ordered production of certain sales and marketing documents. Defendants argue that Judge Leung erred by ordering production of such documents from before June 2005, when the FDA required manufacturers to include new warnings about the early symptoms of SJS / TEN on all ibuprofen labels. Defendants believe this sufficiently establishes that they had knowledge of the risks of SJS /

TEN by June 2005 and renders discovery regarding potential earlier knowledge irrelevant. However, Hodges' claims require a more nuanced understanding of what Defendants knew about the risks and when they knew it. For example, one of Hodges' primary contentions is that Defendants should have adopted a more robust warning than they did. See Am. Compl. ¶¶ 98–106, 135–43. Defendants' pre-2005 sales and marketing documents are relevant for Hodges "to properly contextualize the events and findings leading to the label change," including the decision not to adopt a more robust warning. Discovery Order at 9. Therefore, Judge Leung's Discovery Order compelling production of such documents is neither erroneous nor contrary to law.

IV. CONCLUSION

Based upon the foregoing, and all of the files, records and proceedings herein, **IT IS HEREBY ORDERED** that Defendants' Objections [Docket No. 173] are **OVERRULED**.

All Citations

Not Reported in Fed. Supp., 2016 WL 1222229

Footnotes

1 Ibuprofen is the generic name for the drug Defendants market under the trade name Advil.